REMARKS

The remarks made herein are in response to the Office Action dated April 18, 2007, wherein Claims 1-6 were addressed.

The Examiner's corrections listed on page 3 of the above-mentioned Office Action specify locations that are in reference to the original application submitted on January 22, 2004, whereas the amendments to the specification discussed in the section 'IN THE SPECIFICATION' above, address changes to be made within the substitute specification submitted on June 28, 2004. The requested changes to the specification do not constitute new matter and are supported, at least, by the inherent nature of the original disclosure, i.e. the calculation of percent by weight being inherent to the values provided for the weight of each ingredient and the weight of the total composition.

The Rejections under 35 U.S.C. § 112

Claim 1 has been rejected under 35 U.S.C. 112, second paragraph. In response to the Examiner's rejection, the Applicants have amended the claim and as such, the amended claim is patentable subject matter and ready for allowance.

Claim 3 has been rejected under 35 U.S.C. 112, second paragraph. The Examiner's rejection of Claim 3 states "Claim 3 recites the limitation 'weight' in claim 2" and "there is insufficient antecedent basis for this limitation in the claim. . . In claim 2, the pharmaceutical composition comprises about 50 to less than 150 mg of fluconazole and 1000 mg to less than 2000 mg of secnidazole. However, in claim 3, which is dependent on claim 2, fluconazole is 75% ± 20% in weight of the total pharmaceutical composition."

Applicants have amended Claim 3 to identify the correct percent by weight range for the appropriate compound. The previously presented percent by weight range of 6% ± 20% has been corrected to 6% ± 2%. In addition, it is noted that in previously presented Claim 3 the compounds were inadvertently misplaced. The amended claim identifies the appropriate percent by weight of 75% ± 20% for secnidazole and 6% ± 2% for fluconazole. The amended claim is supported, at least, in the specification on page 21, refer to Example 4, wherein the total weight of the pharmaceutical composition is 660.5 mg, containing 37.5 mg of fluconazole and 500 mg of secnidazole. The subsequent calculation of percent by weight of fluconazole is 5.7% and of secnidazole is 75%. As

discussed above, the percent by weight calculations have been added to the Example Tables in the amendments to the specification. Thus, amended Claim 3 contains sufficient antecedent basis for the limitation from Claim 2 and constitutes patentable subject matter.

For the reasons discussed above, Claim 1 and Claim 3, as amended, are patentable subject matter and ready for allowance.

The Rejections under 35 U.S.C. § 103

Claims 1-3 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lin et al (US 2004/0033968). The Examiner states that "Lin et al. teach compositions containing fluconazole, tinidazole, secnidazole, and the like or a combination thereof. . ." The Examiner also states "Lin et al. teaches compositions contain at least 400 mg of the imidazole anti-fungal compound, which meets the limitations of the instant claims."

Applicant has amended the claims and traverses the rejection. The pharmaceutical composition of the present application contains about 50 mg to about 150 mg of fluconazole (or imidazole anti-fungal compound). The pharmaceutical range for the weight of imidazole antifungal in the semisolid compositions taught by Lin et al is "at least 400 mg", i.e. 400 mg or greater. The pharmaceutical compositions of the present application contain 50 to 150 mg of fluconazole, an amount less than the stated "at least 400 mg" of imidazole anti-fungal compound (or fluconazole). Thus, the composition of Lin et al. does not meet the limitations of the weight range of fluconazole in amended Claims 1-3. As such, the amended Claims 1-3 are patentable subject matter.

The Examiner states that "Lin et al. teach compositions containing fluconazole, tinidazole, secnidazole, and the like or a combination thereof."

The potential combinations of the antifungal and antiamebic compounds suggested by Lin et al. compose a large genus. Lin et al. does not provide any suggestion or explicit teaching regarding a composition with the specific combinations of fluconazole and tinidazole or fluconazole and secnidazole as in the current application. In fact, the preferred embodiments of the semisolid compositions of Lin et al. contain miconazole nitrate, terconazole or metronidazole individually; none of the three compounds used in the combinations in the present application. Furthermore, a person of

ordinary skill reading Lin et al. would not be able to select specific combinations of fluconazole with either tinidazole or secnidazole in the specific amounts presented in the pharmaceutical compositions of the current application without further experimentation.

In addition, Lin et al. teaches semisolid compositions for vaginal administration whereas the present application embodies solid compositions for oral administration. The corresponding formulations, as recited in amended Claims 1-3, and the preparation methods for these variant treatments, oral administration vs. topical application, are quite different and would require more than routine experimentation due to multiple factors, including but not limited to, biological effects on bioavailability caused by drug absorption rates (topical application) and metabolic rates and pathways (oral administration). Thus, although Lin et al. teaches compositions containing fluconazole, tinidazole and secnidazole, there is no explicit teaching to combine the compounds, let alone combining them in the specific amounts of amended Claims 1-3, for an orally administered composition. As such, amended Claims 1-3 are patentable subject matter.

Claims 4-6 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Lin et al (US 2004/0033968) in view of Eichman (US 5,980,882). The Examiner states "Lin et al. do not teach the pharmaceutical compositions for oral administration, table dosage forms, and pharmaceutical vehicles. . . Eichman teaches fluconazole, tinidazole and secnidazole can be made into tablets in a drug resin-complex."

Applicants have amended the claims and traverse the rejection. The teachings of Lin et al., as discussed above, do not provide suggestion or motivation to combine the specific components of fluconazole with tinidazole or secnidazole, nor are they disclosed in the specific amounts present in the current application. Although, Lin et al. teaches an amount of fluconazole in a semisolid composition, it is outside the limitations of the amended Claims 4-6. The drug resin complexes taught by Eichman are different than the solid tablets of the current invention and although Eichman addresses, among the vast quantity of disclosed options, synthetic antifungals (such as fluconazole) and antiamebics (such as secnidazole and tinidazole) there is no suggestion or motivation within Eichman to combine the antifungal and antiamebic compounds in a drug resin complex. In addition, Eichman teaches no pharmaceutically acceptable working concentration range for a solid composition containing a combination of antifungal and antiamebic

medicaments for the treatment of vaginal infections. Thus, the pharmaceutical compositions for oral administration in the present application are not taught by Lin et al. in view of Eichman, as both Lin et al. and Eichman lack a teaching of the specific amounts of antifungal and antiamebic compounds for use in a specific combination of fluconazole and either tinidazole or secnidazole for oral administration to treat vaginal infections. As a result, the amended Claims 4-6 are patentable subject matter.

The Examiner states "Regarding % by weight of fluconazole and secnidazole as recited in instant claim 3, Lin et al. teach the compositions contain 16% by weight of the imidazole anti-fungal compound, which meets the limitations of the instant claims." The applicants respectfully disagree with the Examiner's statement. Amended Claim 3 shows that the acceptable percent by weight range of fluconazole is 6% ± 2%, a limitation percent weight range that is not met by a composition that contains 16% by weight of imidazole anti-fungal compound (fluconazole), such as the semisolid composition of Lin et al. Thus, the pharmaceutical compositions of the present application are not met by those of Lin et al. As such, the amended Claims 5 and Claim 6, both properly dependent on amended Claim 3, are patentable subject matter.

Furthermore, the pharmaceutical compositions of the present application "comprise an association of two active ingredients in lower doses compared to that commonly used for the treatment of vaginal infections" (refer to specification, page 16, lines 18-25). In fact, one of ordinary skill in the art would "expect nothing but a lowering of the therapeutic effect of the medication when the dose is lowered in the amount mentioned, which, as will be shown, does not happen" (refer to specification, page 17, lines 15-18) As shown by the pharmacological examples of the present application, a reduced dosage of antifungal in combination with a reduced dosage of antiamebic is equally effective in treating vaginal infections with less adverse side effects (refer to specification, page 24-25). The combination of a reduced fluconazole dosage with a reduced tinidazole dosage provides an enhancement of activity for treatment of vaginal infections in comparison to the common dosages used for treatment of vaginal infections with the compounds individually. Thus, the unexpected equivalent efficacy and lowered adverse effects provided by the combination of a reduced dosage of fluconazole and tinidazole result in amended Claims 1-6 being patentable subject matter.

It is also noted that the weight range stated in amended Claim 1 of "about 50 to less than 150 mg fluconazole and from about 1000 to less than 2000 mg tinidazole" creates a pharmaceutical composition with a large ratio of (mg fluconazole):(mg tinidazole or secnidazole), on the order of 1:7 to 1:40. This ratio is large and the homogeneity of the product is not an easy problem to solve. Furthermore, at the time of filing it was not obvious for one of ordinary skill in the art to vary the quantity of tinidazole or secnidazole and at the same time to vary the quantity of fluconazole in order to get a homogeneous and effective composition. Thus, in addition to the above discussion, the amended Claims 1-6 are patentable subject matter and ready for allowance.

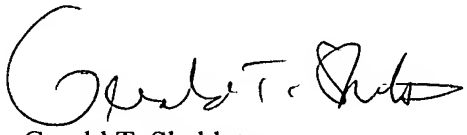
Addition of New Claims

Newly added Claims 13 – 16 are dependent on Claim 1 and reiterate the content of previous claims (3-6) that are dependent on Claim 2. Newly added Claims 17, 19, and 21 are also dependent on Claim 1 and further limit the scope of the invention to the pharmacological examples of the present application and are supported, at least, by Examples 1, 2 and 3 in the specification on pages 19-21. Newly added Claims 18, 20 and 22 are dependent on Claim 2 and further limit the scope of the invention to the pharmacological examples and are supported, at least, by Example 4 in the specification on pages 21-22. For these reasons, as well as the reasons discussion above, Claims 13 - 22 are patentable subject matter and ready for allowance.

Based on the above discussion, applicant hereby requests reconsideration and reexamination thereof.

With the above amendments and remarks, this application is considered ready for allowance and Applicant earnestly solicits an early notice of same. Should the Examiner be of the opinion that a telephone conference would expedite prosecution of the subject application, he is respectfully requested to call the undersigned at the below-listed number.

Respectfully submitted,
WELSH & KATZ, LTD.



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